**DEPARTMENT OF HEALTH AND HUMAN SERVICES** Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

# WARNING LETTER

October 12, 2006

Nutricell, Inc.
653 West Station
Kankakkee, Ill 60901

Dear Sir or Madam:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://www.nutricell.com and has determined that the products Vitamin Research Products Biotin 10mg, Vitamin Research Products Optimum D, and Vitamin Research Products GluControl are promoted for conditions that cause these products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

Examples of some of the claims observed on your web site include:

Vitamin Research Products GluControl

- "Improves Blood Sugar Regulation and Deters Hyperglycemia"
- "May Lower Cholesterol Levels in Type-2 Diabetics and Help Decrease Insulin Requirements"
- "Helps Lower Risk for Obesity, Hypertension, Coronary Artery Disease and Diabetes"
- "Aids in Protecting Against Complications of Diabetes"

Vitamin Research Products Optimum D

- "For People with Diabetes or Those Concerned About Developing Diabetes"
- "Aids in Lessening Insulin Resistance and Lowering Blood Sugar"

Vitamin Research Products Biotin 10mg

- "Assists in Managing and Regulating Blood Sugar Levels"

- "May Help Lower Risk of Certain Cancers and Heart Disease"

- "Possible Aid in Prevention and Control of Non-Insulin-Dependent Diabetes Mellitus (NIDDM-or Type II diabetes)"

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions, and, therefore, they are also "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

These products are also misbranded within the meaning of Section 502(f)(1) of the Act, in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. We noticed that you promoted other products for disease treatment and/or prevention. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your web site, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act.

Failure to promptly correct the violations specified above may result in enforcement action without further notice. Enforcement action may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.

Please advise this office in writing, within 15 working days of receipt of this letter, as to the specific steps you have taken or will be taking to correct these violations, including the steps taken to assure that similar violations do not recur. Include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Your reply should be sent to Quyen Tien, Compliance Officer, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Division of Enforcement (HFS-607), 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

Sincerely,

Joseph R. Baca
Director
Office of Compliance
Center for Food Safety
and Applied Nutrition